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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,311	12/02/2002	Karin Briner	X-11594	8925
7590 04/28/2004			EXAMINER	
Eli Lilly and Company R Craig Tucker			OWENS, AMELIA A	
Lilly Corporate	Center/DC1104	ART UNIT	PAPER NUMBER	
Indianapolis, IN 46285			1625	**

DATE MAILED: 04/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

1) Responsive to communication(s) filed on			Application No.	Applicant(s)				
Amelia A. Owens The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. If the period for reply specified above is less than they (50) days, and specified above is less than they (50) days, and specified above is less than they (50) days, and specified above is less than they (50) days, and specified above is less than they (50) days, and specified above is less than they follow the period of the communication. If the period for reply specified above is less than they follow the period and only and well specified (1) MONTHS from the manage date of this communication. If the period for reply specified above is less than they follow the period and well specified (1) MONTHS from the manage date of this communication. If the period for reply specified above is less than they follow the period and well specified (1) MONTHS from the manage date of this communication. Any reply received by the Office lazer than there months after the maining date of this communication, even if threly filled, may reduce any search particular than discontinuous and the replacement of the communication. Prior this action is FINAL. 2b) ☑ This action is finAL. 2b) ☑ This action is non-final. 3) ☑ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Exparte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) ☑ Claim(s) 1-2 Is/are pending in the application. 4) ☑ Claim(s) 1-2 Is/are allowed. 5) ☑ Claim(s) 1-3 Is/are allowed. 5) ☑ Claim(s) 1-3 Is/are allowed. 6) ② Claim(s) 1-3 Is/are allowed. 7) ☑ Claim(s) 1-3 Is/are allowed. 8) ☑ Claim(s) 1-3 Is/are allowed. 9) ☑ The specification is objected to by the Examiner. 10) ☐ The drawing(s) filled on is/are: allowed. 10) ☐ The drawing(s) filled on is/are: allowed. 11) ☑ The dark nay not reque	Office Action Summary		09/890,311	BRINER ET AL.				
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a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) 1. Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) 1. Information Disclosure Statement(s) (PTO-152)	Priority ι	ınder 35 U.S.C. § 119						
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DETAILED ACTION

Claims 1-8 are pending. No drawings were filed with the application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Schulze-Alexandru et al CA 132:202636.

Schulze-Alexandru et al. teach compounds according to the invention. See RN260809-92-5; 260810-00-2; 260810-27-3.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Ellis et al CA 128:22811. The compounds are useful for treatment of disorders of melatonin-regulated systems.

The reference teaches compounds according to the invention. See RN 199391-54-3; 199391-55-4.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Royer et al CA 78:71948.

The reference teaches compounds according to the invention. See RN 39758-13-9; 39758-14-0; 39758-15-1; 39758-16-2; 39758-17-3.

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Claims 3-8 are not included in the above rejections as the references do not teach or fairly suggest the claimed method of using the compounds.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3 and 6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

- 1) The breadth of the claims,
- 2) The nature of the invention,
- 3) The state of the prior art,
- 4) The level of one of ordinary skill,
- 5) The level of predictability in the art,
- 6) The amount of direction provided by the inventor,

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7) The existence of working examples,

8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The nature of the invention: The nature of the invention is the method for increasing activation of the 5-HT2c receptor in mammals.

The state of the prior art: The state of the prior art is that it involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat which specific disease). There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

The predictability in the art: It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F. 2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, in the absence of a showing of a nexus between obesity and depression and increasing activation of the 5-HT2C receptor in mammals, one of ordinary skill in the art is unable to fully predict possible results from the administration of the compound of claim 1 due to the unpredictability of the role of increasing activation of the 5-HT2C receptor in mammals.

The presence or absence of working examples: There are several examples which prepare compounds of the invention.

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The amount of direction or guidance present: The guidance present in the specification is that of the compounds that it is unclear which compounds were tested. The specification merely recited 'compounds of the invention were tested'. See pages 109-111 were compounds were tested with an effect on obesity.

The breadth of the claims: The claims are drawn to increasing activation of the 5-HT2C receptor in mammals with the compound of claim 1.

The quantity of experimentation needed: The quantity of experimentation needed is undue. One skilled in the art would need to determine which of the claimed compounds would increase activation of the 5-HT2c receptor in mammals thereby treating obesity and/or depression.

The level of the skill in the art: The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

Thus, the specification fails to provide sufficient support of the broad use of the compounds of claim 1 for increasing activation of the 5-HT2c receptor in mammals thereby treating obesity and/or depression. As a result necessitating one of ordinary skill to perform an exhaustive search for which compound of claim 1 increases activation of the 5-HT2c receptor in mammals in order to practice the claimed invention.

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Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, one of ordinary skill in the art would have to engage in undue experimentation to test which diseases can be treated by the compounds of the instant claims, with no assurance of success.

This rejection can be overcome by deleting the claims.

Allowable Subject Matter

Claims 4,5,7 and 8 are allowable. The prior art of record does not teach or fairly suggest the claimed invention.

Compounds where R4/R4' and R5/R5' form a cyclopropyl group are not taught or fairly suggested by the prior art of record.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amelia A. Owens whose telephone number is 571-272-0690. The examiner can normally be reached on Monday - Friday from 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amelia A. Owens Primary Examiner Art Unit 1625